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14. 510(K) SUMMARY

Applicant:	Biosense Webster, Inc. 3333 Diamond Canyon Rd. Diamond Bar, CA 91765, USA Phone: 800-839-8599 Fax: 909-839-8804
Date:	January 19, 2009
Contact Person:	Balaka Das Senior Specialist, Regulatory Affairs
Proprietary Device Name, Manufacturing Part Number:	REFSTAR® PLUS with QWIKPATCH® External Reference Patch, D-1210-03 REFSTAR® PLUS Cable, M-4700-106
Common Device Name:	Surface Reference Device
Classification Name:	Electrode Recording Catheter (per 21 CFR 870.1220, Product code DRF
Predicate Device:	REFSTAR® External Reference Patch (K061468) Interface Cable (K982415)
Manufacturing Facilities:	REFSTAR® PLUS with QWIKPATCH® External Reference Patch Biosense Webster, Inc. Circuito Interior Norte #1820 Parque Industrial Salvacar Juarez, Chihuahua Mexico 32599 Biosense Webster, Inc. 15715 Arrow Highway Irwindale, CA 91706

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REFSTAR® PLUS Cable
Biosense Webster (Israel) Ltd.
POB 2009
4 Etgar Street, Einstein Bldg.
Tirat HaCarmel, 39120
Israel

14.1 Description of Device

The Biosense Webster REFSTAR® PLUS with QWIKPATCH® External Reference Patch is an integral part of a non-fluoroscopic catheter tip location and electrogram capture technology called CARTO® and NOGA®. When used with the CARTO® and NOGA® systems, the location of the navigation catheter tip is compared to the location of this reference patch. This reference device consists of a sensor embedded in an adhesive patch at the distal end of a shaft, which connects to a connector at the proximal end of the shaft. The connector connects to the REFSTAR® PLUS Cable, which houses a printed circuit board and an EEPROM (Electrically Erasable Programmable Read Only Memory). The REFSTAR® PLUS Cable connects the REFSTAR® PLUS with QWIKPATCH® External Reference Patch to the Patient Interface Unit (PIU) of CARTO® and NOGA® EP Navigation Systems.

14.2 Indications for Use

REFSTAR® PLUS with QWIKPATCH External Reference Patch:
The Biosense Webster REFSTAR® PLUS External Reference Patch is indicated for use with the Biosense Webster navigation catheters and the CARTO® and NOGA® Systems to provide a reference point for catheter tip location.

REFSTAR® PLUS Cable:
The REFSTAR® PLUS Cable provides a means to connect between a Biosense Webster electrophysiology REFSTAR® PLUS with QWIKPATCH® External Reference Patch and the Patient Interface Unit (PIU). This cable may be re-used.

14.3 Summary of Testing

The REFSTAR® PLUS with QWIKPATCH® External reference Patch and REFSTAR® PLUS Cable have passed bench testing to validate the mechanical and electrical integrity of the devices and the performance of the devices with the CARTO® and NOGA® Systems.

14.4 Substantial Equivalence

The REFSTAR® PLUS with QWIKPATCH® External Reference Patch and REFSTAR® PLUS Cable are substantially equivalent to the predicate REFSTAR® with QWIKPATCH® External Reference Patch and Interface cable in terms of intended

use, operating principles, fundamental scientific technology, design and performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 4 2009

Biosense Webster, Inc.
c/o Mr. Balaka Das
Senior Specialist, Regulatory Affairs
3333 Diamond Canyon Road
Diamond Bar, CA 91765

Re: K090120
Trade Name: REFSTAR(R) PLUS with QWIKPATCH(R) External Reference Patch
REFSTAR(R) PLUS Cable
Regulation Number: 21 CFR 870.1220
Regulation Name: Electrode Recording Catheter
Regulatory Class: Class II (two)
Product Code: DRF
Dated: March 4, 2009
Received: March 5, 2009

Dear Mr. Das:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K090120

5. INDICATIONS FOR USE

510(k) No (if known): K090120

Device Name: REFSTAR® PLUS with QWIKPATCH® External Reference Patch
REFSTAR® PLUS Cable

Indications for Use:

REFSTAR® PLUS with QWIKPATCH® External Reference Patch:
The Biosense Webster REFSTAR® or REFSTAR® PLUS External Reference Patch is indicated for use with the Biosense Webster navigation catheters and the CARTO® and NOGA® Systems to provide a reference point for catheter tip location.

REFSTAR® PLUS Cable:
The REFSTAR® PLUS Cable provides a means to connect between a Biosense Webster electrophysiology REFSTAR® PLUS with QWIKPATCH® External Reference Patch and the Patient Interface Unit (PIU). This cable may be re-used.

Prescription Use √ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K090120